REMARKS

The remainder of this Amendment is set forth under the appropriate subheading for the convenience of the Examiner.

I. Claim Status

The instant patent application includes thirty-two (32) pending claims with entry of the above amendment. Claims 1, 12, 19, 24, and newly added Claim 25 are the five (5) independent claims. Claims 2 through 11 and new Claims 26 through 28 depend from Claim 1. Dependent Claims 13 through 18 depend from independent Claim 12. Claims 20 through 23 and new Claims 29, 30 and 32 depend from Claim 19. New Claim 31 depends from Claim 24.

II. Amendment to the Claims

Applicants have amended Claims 1 through 5, 12, 13, 15, 20, 21, 23, and 24. Claim 1 has been amended to now recite, 'a device for modulating an impedance of an orthotic joint throughout a walking cycle for treating an ankle foot gait pathology." Support for the amendment of Claim 1 can be found in the patent application as originally filed at, for example, page 4, lines 10 through 15. No new matter is added by the amendment. Claims 2 and 3 have been amended to have the correct antecedent basis to Claim 1.

Claim 2 now recites that the device includes an actuator that controls stiffness to achieve a spring-damper positional control. Claim 3 presently recites that the device includes an actuator that controls at least one of spring stiffness, spring damping, or both. Support for these amendments can be found in the patent application as originally filed at, for example, page 3, lines 23 through 26.

Claim 12 is amended to remove the limitation that the actuator is attachable to the leg portion and also to remove the limitation that the spring is disposed between the actuator and the foot portion. Claim 12 now recites that the actuator is configured to act on a spring to modulate an impedance of the orthotic joint. Support for this amendment can be found in the patent application as originally filed at, for example, page 4, lines 15 through 21, page 3, lines 4 through 12, and at FIG. 1.

Claim 13 is amended to recite that the actuator adjusts the stiffness of the orthotic joint by controlling spring deflection during controlled plantar flexion to minimize forefoot collisions with the ground. Support for this amendment can be found in the patent application as originally filed at, for example, page 4, line 16 and line 20. The remaining claims include similar limitation and are fully supported in the patent application at the above noted locations. No new matter is added.

New Claims 26 through 28, 30 and 31 recite that the method and apparatus of the present invention, as claimed, modulates an impedance of the orthotic joint by controlling a spring, which is linked to the actuator by controlling stiffness of a torsional spring control, a spring damping, or both. Support for new Claims 26 through 31 can be found in the specification as originally filed at, for example, page 4, lines 9 through 21 and in reference to FIG. 1. Other dependent claims are amended to include correct antecedent basis to the independent claim from which they depend.

New Claim 29 is added to include the steps of "operatively coupling a spring to an orthotic joint of an orthosis" and to include "sensing one or more parameters of the orthotic joint throughout a walking cycle." Support for new Claim 29 can be found at, for example, page 5, lines 5 through 24 and at page 4, line 27 through page 5, line 4. Support for new Claim 32 can be found at, for example, page 8, line 1 through page 9, line 18.

No new matter is added.

III. Rejection of Claims 1-5, 10-15, 18-22 and 23 under 35 U.S.C. §102(b)

Claims 1 through 5, 10 through 15, 18 through 22 and 23 are rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 5,112,296 to Beard *et al.* (hereinafter "Beard *et al.*"). Specifically, the Examiner stated that Beard *et al.* teaches a variable-impedance active ankle foot orthosis that includes an elastic actuator coupled to a foot portion of the orthosis for modulating an impedance of an orthotic joint throughout a walking cycle and for treating an ankle foot gait pathology. The Examiner also stated that Beard *et al.* teach torsional spring control and a spring-damper positional control.

Applicants claim a variable-impedance active ankle foot orthosis device. In one embodiment, the device includes an actuator and a spring. The spring is linked to the actuator.

The actuator modulates an impedance of an orthotic joint by controlling the spring. One embodiment of the claimed invention is described at pages 4 through 5 with reference to FIG. 1. With respect to that embodiment, the actuator 12 includes a brushless DC motor operatively connected in series with a spring. The actuator provides force control by controlling the extent that the spring is compressed. The orthosis device also includes a metal hinge that permits selective rotation. The orthosis device further includes sensors 14 and 16, or more particularly, a ground reaction sensor and an ankle angle sensor to provide feedback to the actuator, which then modulates an impedance of an orthotic joint by controlling the spring.

Beard *et al.* disclose a biofeedback activated orthosis. The orthosis is configured for foot-drop rehabilitation. The orthosis includes foot brace 2 secured to the foot of the user that includes lifting cable 3 for lifting foot 54 throughout a gait cycle. (Col. 4, lines 40 through 43). Beard *et al.* also disclose a device 8 for sending a signal to a controller to represent an angular relationship between the lower leg and the thigh. (Col. 4, lines 60 through Col. 5, line 3). If both muscle activity parameters and the angular relationship parameters between the lower leg and the thigh are met, then a processing signal is sent to activate geared motor 29 to timely apply tension to the cable and to pull upwardly foot brace 2. (Col. 5, lines 48 through 58). Backlash inhibiting device 67 prevents backlash of cable 3 by maintaining a minimum amount of tension in cable 3 at all times. Backlash device 67 of Beard *et al.* includes screw 68 placed into protruding portion 79 of base plate 28 with coil spring 69 that is wound about it and fixed at its base to base plate 28. Spring washer 75 is used to retain the body of coil spring 69 on screw 68. Spring arm 70 of coil spring 69 extends from screw 68 to cable 3 and contains spring loop 71 through which cable 3 remains in slidable communication.

Beard *et al.* do not disclose or suggest any variable-impedance active ankle foot orthosis that includes a device for modulating an impedance of an orthotic joint. The spring described in Beard *et al.* is not controlled by an actuator or device whereby an impedance of an orthotic joint is modulated. The Beard *et al.* spring does not modulate any impedance of the orthotic joint nor is it controlled as presently claimed in independent Claims 1, 12, 19 and 24. Reconsideration and withdrawal of the rejection of Claim 1 are requested. Claims 2 through 5, and 10 through 11 depend from Claim 1 and are patentable as these claims depend from an allowable base claim. Dependent Claims 13 through 15 and 18 are patentable as these claims depend from independent

Claim 12. Claims 20 through 23 are also patentable as these claims depend from independent Claim 19.

IV. Rejection of Claim 24 under 35 U.S.C. §102(b)

Claim 24 is rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 5,643,332 to Stein (hereinafter "Stein"). In the alternative, Claim 24 is also rejected under 35 U.S.C. §102(e) as being anticipated by United States Patent No. 6,507,757 to Swain *et al.* (hereinafter "Swain *et al.*"). The Examiner stated that Stein outlines a FES stimulator device and method which modulates ankle impedance during the swing phase of a walking angle, inherently providing control during the controlled plantar flexion and minimizes forefoot collisions, and that Swain *et al.* clearly disclose the invention as claimed.

Amended Claim 24 includes the limitation of modulating stiffness. Claim 24 further requires that the modulation is sufficient to achieve a torsional spring control during controlled plantar flexion so as to minimize forefoot collisions with the ground, and to actively modulate stiffness, damping, or both to achieve a torsional spring-damper control during a swing phase.

Stein teaches an electrical stimulation device which causes a depolarization of the underlying membrane, which causes propagation of an impulse along the nerve and contraction of the muscle. Swain discloses an electrical stimulator for attachment to a leg. The stimulator includes electrodes for attachment to the leg to apply an electrical stimulus. The stimulator also includes a foot switch for sensing foot rise or foot strike. A circuit is responsive to the foot switch and generates stimulation pulses in response to the rise or strike.

Neither Stein nor Swain *et al.* disclose or suggest modulating the stiffness, or damping by controlling a spring, as in the method claimed by Applicants. The method of Claim 24 is novel under 35 U.S.C. §102(b) and, therefore, reconsideration and withdrawal of this rejection are respectfully requested.

V. Rejections of Claims 6 through 8, 16 and 17 under 35 U.S.C. §103(a)

Claims 6 through 8, 16 and 17 are rejected under 35 U.S.C. §103(a) in view of Beard *et al.*, and in the alternative, under U.S. Patent No. 6,966,882 (Horst), U.S. Patent No. 5,643,332 (Stein) and U.S. Patent No. 6,517,503 (Naft *et al.*). In particular, the Examiner stated that Beard

et al. disclose an angle sensor capable of being used on the ankle and that since a knee angle inherently has a correlated and consistent ankle angle during the standing phase, meaning that the angle of the knee is synonymous with measuring the correct ankle angle. The Examiner also stated that, as indicated by Beard *et al.*, Stein, and Horst, angle sensors are well known in the art, as are ground reaction force sensors in the foot orthosis art, as indicated by Horst, Swain *et al.* and Naft *et al.* The Examiner stated that it would have been obvious to modify the system taught by Beard *et al.* with the devices described by the surrounding references. Claims 6 through 8 are dependent from Claim 1 and Claims 16 and 17 are dependent from independent Claim 12.

As discussed above, there is no disclosure or suggestion in Beard *et al.* of Applicants' claimed variable impedance action ankle foot orthosis, wherein a spring linked to an actuator is controlled to modulate an impedance of the orthotic joint. The subject matter of Applicants' invention of Claims 1 and 12 meet the criteria under 35 U.S.C. §§102(b) and 103(a) in view of Beard *et al.* Therefore, the subject matter of dependent Claims 6 through 8, and 16 and 17 also meet the requirement of novelty and non-obviousness under 35 U.S.C. §§102(b) and 103(a).

None of Horst, Stein, Swain *et al.* or Naft *et al.* remedy the deficiencies of Beard *et al.* Therefore, the subject matter of Claims 6 through 8, 16, and 17 meet the requirement of non-obviousness and 35 U.S.C. §103(a).

VI. Rejection of Claim 9 under 35 U.S.C. §103(a)

Claim 9 is rejected under 35 U.S.C. §103(a) as being unpatentable over Beard *et al.* in view of Swain *et al.* and in further view of Naft *et al.* The Examiner stated that it would have been obvious to one of ordinary skill in the art to modify the system of Beard *et al.* with the foot switch of Swain *et al.*, or Naft *et al.* to provide the Beard *et al.* system with the same advantage of improving patient gait and treating foot drop.

Naft *et al.* further discloses a selectively lockable orthotic knee joint that includes a pressure sensor. The orthotic knee joint includes a spring washer that biases a first ratchet plate 50 from a second ratchet plate 38.

Neither Swain *et al.* nor Naft *et al.* cure the deficiencies of the primary reference or disclose or suggest device that includes a spring linked to an actuator with the actuator modulating an impedance of an orthotic joint by controlling the spring as presently claimed in

Claim 1. Naft *et al.* do not disclose or suggest any device modulating an impedance of an orthotic joint as presently claimed in Claim 1.

VII. New Claims

New dependent Claims 26 through 32 depend, directly or indirectly, from independent Claims 1, 19, or 24. They are all directed to modulating impedance by controlling stiffness of a torsional spring control of a spring linked to an actuator of a variable impedance active ankle foot orthosis. None of the references, separately or in any combination, disclose or suggest the subject matter of the new claims. Therefore, Applicants respectfully request that these claims also be considered and allowed to pass to issuance.

Newly added independent Claim 25 is patentable over the cited and relied upon references. Support for Claim 25 can be found in the specification as originally filed at, for example, page 4, lines 9 through 21 and in reference to FIG. 1, and further at page 6, lines 21 through 29. None of the references alone or in combination with one another disclose or suggest any spring operatively linked to the actuator with the actuator modulating an impedance of an orthotic joint by controlling a compression of the spring in response to a sensed parameters throughout a walking cycle, or that the actuator modulates the impedance of the orthotic joint by controlling the spring in at least three different modulation phases of the walking cycle.

CONCLUSION

In view of the above amendments and remarks, it is believed that all of the pending Claims are in condition for allowance. It is respectfully requested that all of the outstanding rejections be reconsidered and withdrawn, and that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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